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IN UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michael Douglas Spears, M.S.

Filed: 28 February 2002

Serial No: 10/070,342

Confirm No: 2921

Docket: SPER -100A

For: Tool and Method for Cutting
Powered by an Electromagnetic (EM)
Source

Examiner: A. F. Roane

Group Art: 3739

) I hereby certify under 37 CFR 1.8 that a signed original copy of
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) Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450
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) By: Jean Maccheret (printed name)

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TECHNOLOGY CENTER R3700

Dear Sir:

I, Robert M. Mentzer, Jr., M.D., a citizen of the United States, hereby declare and state:

THAT I am familiar with the handheld-sized probe for cutting and cauterizing tissue pictured and explained by Mr. Michael Spears in his published US patent application entitled "*Tool and Method for Cutting Powered by an Electromagnetic (EM) Source*", No. 10/070,342—a copy of which I've seen.

THAT I am a licensed physician, professor of surgery, having received my medical degree from the University of Maryland. My specialty is Cardiothoracic Surgery.

THAT I am also familiar with, and I have personally used several types of different soft and/or hard tissue cutting cauterizing techniques commonly used and approved for use in the U.S. for human and veterinary surgery; and have a theoretical understanding and practical experience with these tools and techniques. My recognized expertise is based on clinical experience.

THAT I am not an inventor of the technology covered by the patent application currently being examined; and I am not an employee or consultant affiliated with the inventor, Michael Spears.

THAT I have reviewed the details of the figures shown on the next pages and associated description in the Yamanashi Patent No. 6,059,781 (the "later" Yamanashi patent) as well as in the earlier patent to Yamanashi No. 5,019,076 with the foot pedal design; and I have reviewed the details of the figures and associated description to Esty, Patent No. 4,032,738 shown also on the following pages. These patents show traditional designs with switch mechanisms far from the probe, itself. They each have designs quite different from that shown in Mr. Spears's patent application where the switch is on the handheld probe body. None of the patents show a design similar to Mr. Spears's design.

THAT in his published patent application Mr. Spears discusses the design of the earlier Yamanashi patent, stating:

Known early-generation surgical tools include the electromagnetic field focusing (EFF) probe and the later-developed electroconvergent cautery (ECC) system, both of which include a system of large, complex external subassemblies; for reference, see FIG. 1 which is a block diagram illustrating the current EFF system setup; and for the ECC system setup, see Patil, A.A., Yamanashi, W.S. "Electroconvergent Cautery" *Neurosurgery*, Vol. 35, No. 4 (October 1944): 785-788. In either case, the handheld probes associated with the EFF or ECC systems (in FIG. 1, EFF probe is labeled P) merely include a hot tip for cutting, wiring that extends the length of the probe handle, a vacuum tube attached to an external vacuum source to aid in the removal of vaporized tissue and fluids generated at the hot tip of the probe during operation, and an electrical connector at the other end of the probe handle for connecting to the external, complex impedance matching assembly (such as that represented in FIG. 1 and labeled IMN). A separate probe ON/OFF foot pedal, labeled FP in FIG. 1, is electrically hardwired to the probe system for use by a surgeon. Unfortunately, the foot pedal switch and the separate probe tuner of the known system are awkward—taking up much-coveted space in an operating room. Furthermore, not only is it difficult for a surgeon to locate, without the benefit of direct visual aids, the foot pedal of these prior devices while concentrating on handling and focusing the probe to cut the necessary area of tissue, but once the foot pedal is located, a surgeon's foot can ~~accidentally~~ accidentally fall-off of the pedal— which of course can create very dangerous situations during surgery causing inadvertent injury [*as corrected*].

Unlike these known proposed cutting systems, one can readily appreciate the efficient, streamlined design of the handy novel tool and method for cutting of the invention. It is important to note that the new tool preferably has a switch incorporated with a handheld-sized probe housing, as well as impedance matching circuitry encased within the probe housing to help transform load impedance into the characteristic impedance of the input RF power to obtain maximum power transfer (impedance matching) and improve coupling efficiency of the tool network, all of which make the new tool more convenient to a user. ...

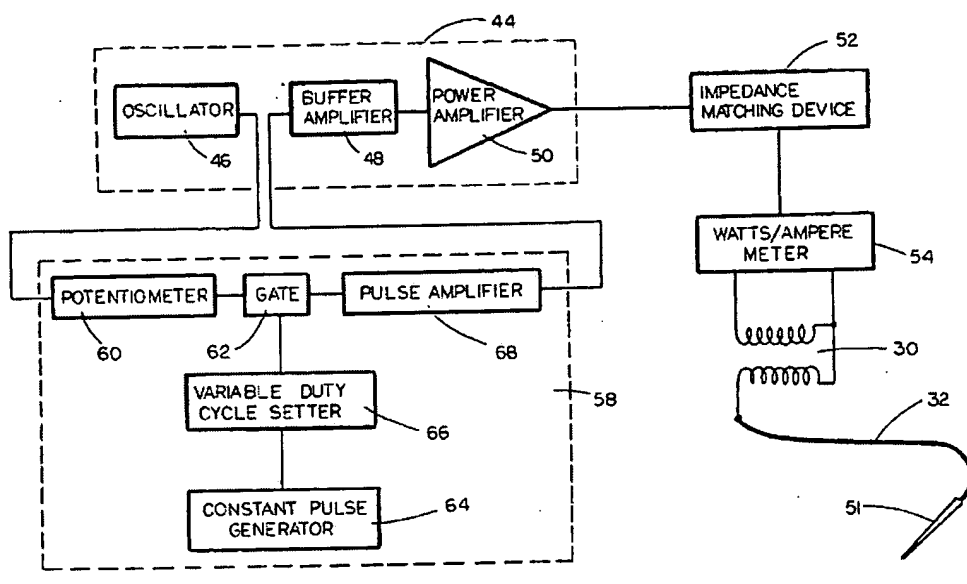


FIG. 6

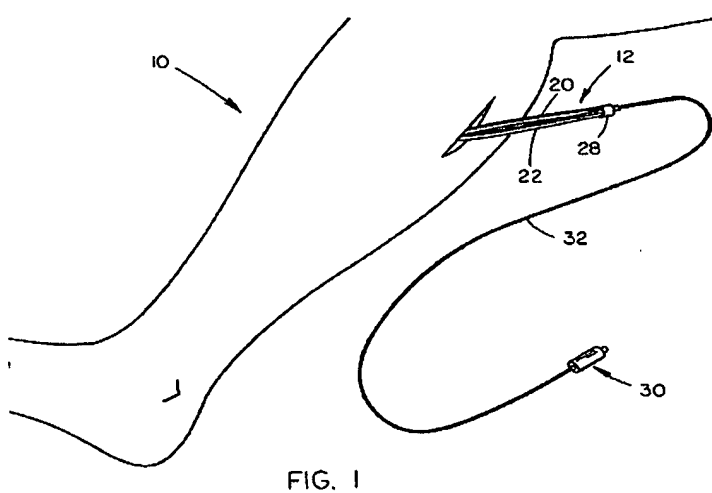


FIG. 1

See next page for discussion

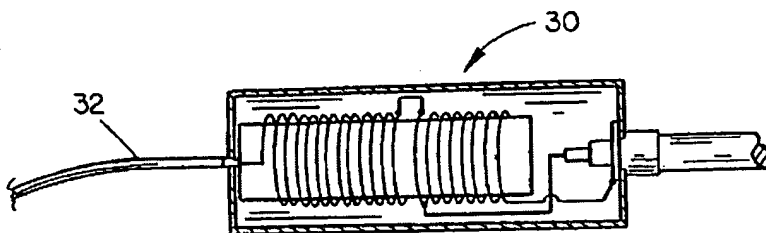


FIG. 7

6,059,781 Yamanashi US Patent

Column 4

The surgical forceps 12 illustrated in FIG. 2 comprises a pair of straight blades 20 and 22 which are insulated except for the tips 24 and 26. Blades 20 and 22 are separated at their proximal ends by a heavily insulated material referred to generally by the reference numeral 28. Blade 20 serves as the active blade and is connected to the loading and tuning coil 30 by means of a heavily insulated cable 32. Blade 22 is passive and has no electrical connections. As seen in FIG. 2, blades 20 and 22 taper towards their sharply pointed tips. Tip 24 of blade 20 is approximately 0.25 mm longer than the tip of the passive blade 22.

With respect to FIG. 3, the surgical forceps 14 illustrated therein are generally similar to the forceps shown in FIG. 2 except that the blades 34 and 36 are bayonnetted. Blade 34 is the active blade and is electrically connected to the insulated cable 32. As in the surgical forceps 12, the tips of the active blade 34 is approximately 0.25 mm longer than that of the tip of the blade 36.

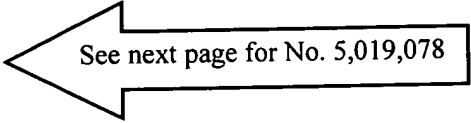
FIG. 4 illustrates a laparoscopic forceps which is similar to the surgical forceps of FIGS. 2 and 3 above except that the blades 38 and 40 are short with the main stems thereof being quite long. Blade 38 is operatively connected to the insulated cable 32.

The surgical probe 18 illustrated in FIG. 5 comprises a rigid wire 42 with a tapered fine tip 43. Except for approximately 5 mm of the tip 43, the remainder of the probe is insulated in pencil shaped configuration for gripping purposes.

An endoscopic probe may also be provided which is generally similar to the surgical probe 18 of FIG. 5 except that the tip portion thereof may be straight, curved or angled. The outer diameter of the probe would be approximately 0.75 to 2 mm. The length of the probe would be a multiple of 22 and may be rigid or flexible. This probe may be used as a resectoscope or as an endovascular probe. Further, the probe could have its tip bent at a right angle.

The cautery instruments of FIGS. 2, 3, 4 and 5 are to be utilized with electrical circuitry illustrated in FIG. 6 and 7. Inasmuch as many of the components of that shown in FIG. 6 are identical or similar to that taught in U.S. Pat. No. 5,019,076, reliance upon said patent is made to complete this disclosure, if necessary. In other words, the parameters or specifications of the various components of FIG. 6 will not be described since it is believed that the same are disclosed in U.S. Pat. No. 5,019,076 or would be obvious to one having ordinary skill in the art.

The numeral 44 refers to a radio frequency power generator comprises an oscillator 46, buffer amplifier 48 and power amplifier 50. As seen in FIG. 6, an impedance matching device 52 is electrically connected to the radio frequency power generator. A watts/ampere meter 54 is electrically connected to the impedance matching device 52 and is electrically connected to the loading and tuning coil 30. Loading and tuning coil 30 is connected to the surgical instrument SI by means of the heavily insulated cable 32. As stated, the surgical instrument SI may be comprised of those instruments previously described. The cable 32 connects the surgical instrument SI to the loading and tuning coil 30 as described and would have a length of 110 centimeters or a multiple of 22.



See next page for No. 5,019,078

U.S. Patent

May 28, 1991

Sheet 7 of 7

5,019,076

This is the earlier Yamanashi design referenced in the later Yamanashi patent.

Only shows a foot pedal switch.

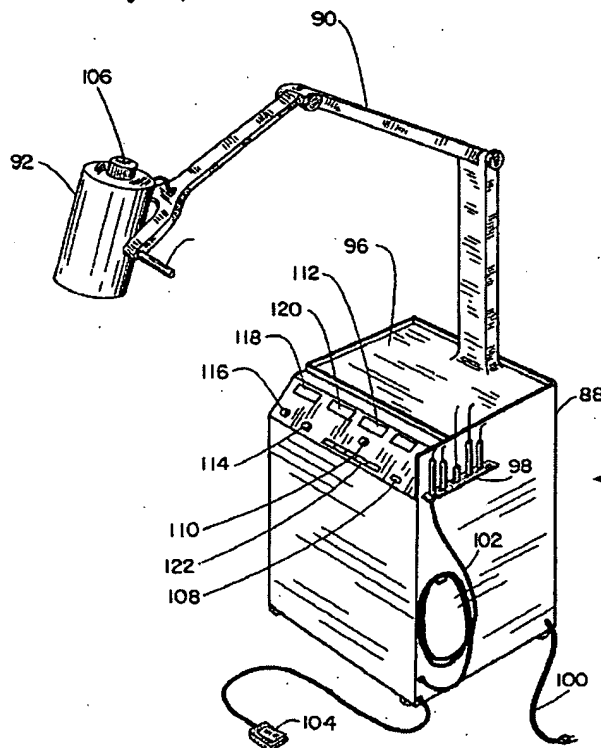


Fig. 9

probes connected with cable

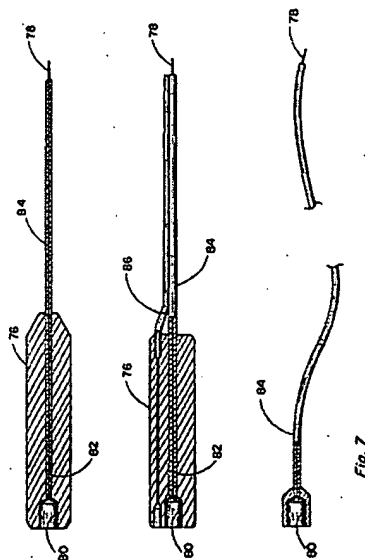


Fig. 7

FIG. 9 illustrates another particularly preferred embodiment of the overall RF surgical tool compatible with and suitable for use in an operating room. As illustrated, the surgical unit comprises a cabinet 88 mounted on casters for ease of positioning the flexible arm 90 with inductive applicator 92 (solenoidal coil with variable capacitor) directly over a patient during surgery. To assist in positioning the coil within the applicator near the tissue to be surgically treated, a manual handle 94 is provided to rotate the solenoidal coil and raise/lower or extend/retract the solenoidal coil along the flexible arm. The top of the cabinet 88 is conveniently used as a tray 96 with the plurality of interchangeable EHF probes 98 mounted to one side of the cabinet 88. A conventional 120 volt (30 amps) grounded plug is used as the sole source of power for the RF generator, vacuum source and ancillary equipment mounted within the cabinet 88.

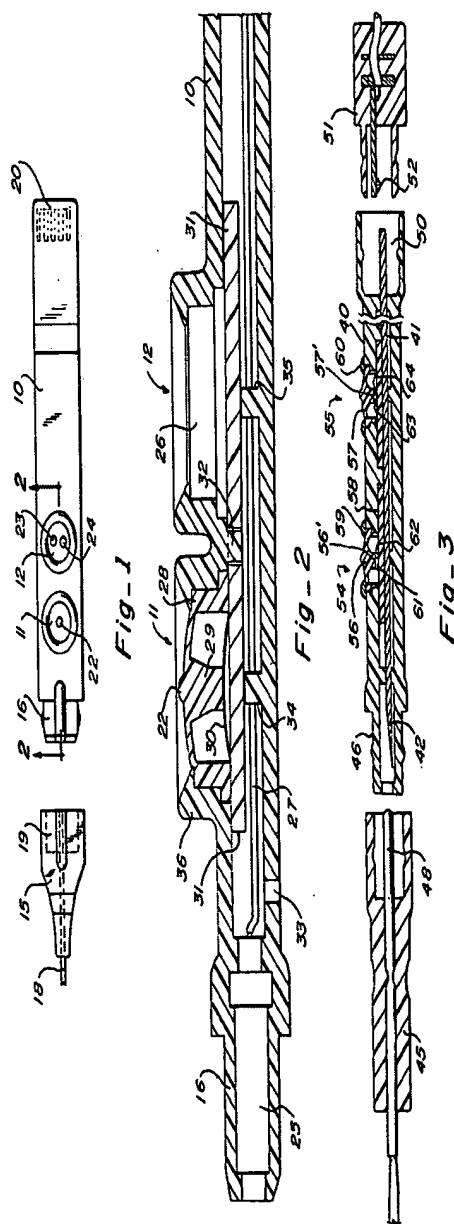
During use of the equipment, the selected probe 98 is attached to grounded cable (with vacuum tube) 102 and held by the surgeon with the inductive applicator 92 positioned over the patient. The surgeon then uses foot pedal 104 to turn the RF field generator on and off as desired. The variable capacitor setting for adjustment for the inductive applicator is provided as a knob 106 near the manually positioned solenoidal coil. The rest of the electronic adjustments and meters are provided on the instrument panel of the cabinet and include typically, a power on/off switch 108; a probe tuner knob 110 with probe current meter 112, an analog load 114 and analog tuner 116 adjustment knobs with RF power meter 118 and VSWR power meter 120; along with a set of preset power level switches 122 for different probe types.

U.S. Patent

June 28, 1977

4,032,738

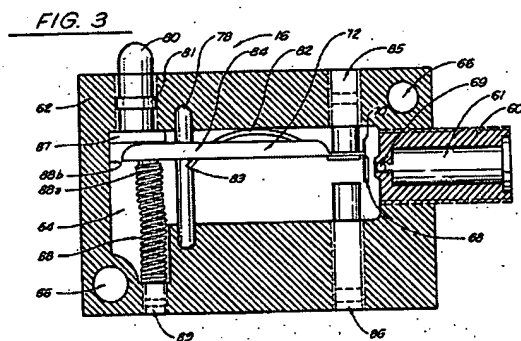
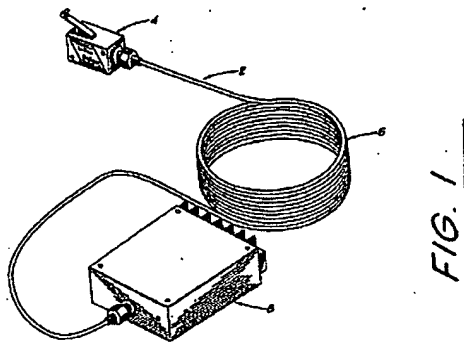
Esty Patent -- Column 3



The main housing 10 is arranged in a substantially flat elongated configuration. This housing more nearly approximates the flat handle feel of previous passive surgical instruments but still incorporates selector switches 11 and 12 near the end thereof so that the surgeon can select the desired electro-surgical procedure without movement of the instrument. At one end, replaceable chuck 15 is arranged so as to cooperate with the generally flat extension 16 from the body 10 in substantially the same manner as has been described in greater detail in the aforementioned cross-referenced application entitled *Detachable Chuck For Electro-Surgical Instruments* by J. M. Esty. As described in that application, chuck 15 has an exposed surgical electrode 18 which extends through the insulating body of chuck 15 so as to protrude within cavity 19. Thus the insulating shoulders of the chuck insert extension 16 on body 10 cooperates with chuck 15 so as to provide physical support as between the insulating sidewalls thereof while electrode 18 establishes a sliding contact for electrical current transmission therebetween but with this contact being substantially isolated from the environment of the surgery being performed. Although electrode 18 has been shown without the portion thereof which provides the passive and/or electro-surgical function such as a scalpel blade, wire loop or the like, it will be readily understood that any of these devices can be incorporated for the exposed portion of the electrode 18.

The broad general function performed by frame 10 with chuck 15 attached is to permit momentary switch actuations via switches 11 and 12 which are transmitted through a cable attached to socket 20 and then to an electro-surgical generator. The actuation of either of switches 11 or 12 in a typical application results in selection of a generally continuous high frequency signal as when switch 11 is actuated or a series of short RF pulses as when switch 12 is actuated. Whichever of these signals has been selected is returned from the signal generator through the cable (not shown) into socket 20 and thence through the housing 10 and into electrode 18 of chuck 15. In the particular example illustrated, selection of switch 11 produces a high frequency pulse for procedures such as tissue cutting with a wire loop at electrode 18 whereas selection of switch 12 effects a pulse selection into electrode 18 to provide cauterizing or coagulating functions.

THAT I have also reviewed the pictures, below, and associated description of the Anderson Patent No. 4,607,161 called FIBEROPTIC SWITCH SYSTEM. There is nothing in this patent that suggests anything about electro-surgical instrumentation.



Column 4

INVENTION

Referring to FIG. 1, there is shown at 2 a fiberoptic switch system for monitoring an external condition or stimuli, such as the position of a switch or moving part or some other physical condition which is desired to be monitored. Fiberoptic switching system 2 includes an optical switch 4 which detects changes in the monitored external condition, transmitting optical information or data signals via fiberoptic cable 6 to an electro-optic unit 8 where data from the switch 4 may be processed and stored or displayed.

ABSTRACT

[57]

A fiberoptic limit switch system comprising a light source, an optical beamsplitting arrangement, a switch, an optical fiber, a detector, and output circuitry. The light source is a light-emitting diode. The switch is responsive to external stimulus. The switch comprises a housing, a receptacle for receiving the optical fiber, and a reflective surface movable between two positions within the housing. The optical fiber extends from the light source to the switch. The detector is arranged so as to receive light from the optical fiber and transmit a signal relative to the light emission. The output circuitry is electrically connected to the detector.

Column 5

4,607,

5

switch 16 through connector 60. The exterior of connector 60 is designed so as to receive a male connector attached to the optical fiber. A housing arranged about the end of the optical fiber 15 is adapted to be received by orifice 61 of connector 60. When connected, the end of optical fiber 15 is received by connector 60 as seen in FIG. 5.

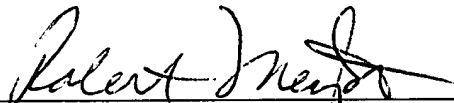
Switch 16 is formed by housing 62 having internal cavity 64. Housing 62 may be made of metals or plastics or other materials particularly suitable to the environment to which the switch will be subjected. Typically, the housing 62 is made of two sections connected together by glue, welds, bolts, or other means. As shown in FIGS. 3 and 4, these sections are connected together by screws fitted into areas 66.

FIGS. 3 and 4 illustrate the preferred embodiment of switch 16. The end of optical fiber 15 is coupled to

THAT technological discussion and illustrations in the various patents are missing features of Mr. Spears's patent application, and where the patent does reference a resistively heated thermal cutting and coagulating surgical instrument that can fit and be held in a human hand, in every case, certain components of the instrument shown are built as *separated* features from the handheld unit portion—and all are missing any suggestion or comment showing a switch mechanism on the probe unit.

THAT at the end of Mr. Spears's published patent application, are claims that state: "said impedance matching circuit is encased by a handheld-sized probe housing, and said switch-contact area is encased by said housing [claim 1]" and "providing RF power from the source to an impedance matching circuit electrically connected to a conductive cutting tip through a switch-contact area, said circuit and said switch-contact area being encased by a handheld-sized housing for the probe [claim 14]." This design of Mr. Spears provides for much greater control and flexibility to users, especially in light of the other patents shown here.

THAT I hereby declare that all statements made herein, in this 8-page DECLARATION, are of my own knowledge and that I have done my best to ensure they are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this patent application or any patent issuing to M. Spears thereon.

Signature: 
Typed name: Robert M. Mentzer, Jr., M.D.

Signed this: 15 day of the month December in year 2003

The signing of this document
was witnessed by (signature): _____
Typed name: Mary Faulkner